5:1, in which the said composition is mixed at a temperature sufficient for the at least partial melting of the not cross-linked SIS elastomer, and in which the said composition is thereafter formed into the said articles.

72. The process of claim 71, in which the said composition contains at least one additive selected from the group consisting of dyes, pigments and mixtures thereof and having a melting point corresponding substantially to the melting point of the not cross-linked SIS elastomer, in which a control of the additive distribution in the formed articles is carried out, and in which the mixing step is controlled so as to reach a substantially homogeneous distribution of said additive in a part of the composition just before its formation into the said article.

73. The process of claim 71, in which the said article is sterilized by a treatment selected from the group consisting of heating at a temperature of at least 121°C during at least 100 minutes, irradiation with a γ-irradiation of at least 20 KGray, and combinations thereof.

REMARKS

Applicant submits herewith a Preliminary Amendment for entry prior to computation of the fees and examination of the application on the merits. Applicant believes the amendment submitted herewith conforms the application to U.S. practice and it is believed that the amendment to the claims place them in allowable form. Early entry of the Notice of Allowance is courteously requested. Should this amendment necessitate any additional fees it may be charged to Deposit Account No. 19-0522.

Respectfully submitted,

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(Docket No. 32396)

Title: THERMOPLASTIC COMPOSITION
Inventors: Kersten, Jean et al.
U.S. National Phase Application corresponding to
International Application PCT/EP99/05988
Attorney Docket No.: 32396

MARKED UP COPY OF PRELIMINARY AMENDMENT TO SHOW CHANGES MADE

SPECIFICATION

Please amend the specification as follows:

At page 1, line 2, please insert the heading:
-- Background of the Invention
1. Field of the Invention --.

At page 1, line 5, please delete "The prior art" and the underlining and substitute:
-- 2. Description of the Prior Art --.

At page 2, line 1, please delete "Brief description of the invention" and the underlining and substitute therefor:
-- Summary of the Invention --.

At page 10, line 17, please delete the underlining beneath the heading "Brief description of the drawings" so that it reads -- Brief description of the drawings -- .

At page 11, line 1, please delete the underlining beneath the heading "Examples of compositions according to the invention" so that it reads -- Examples of compositions according to the invention -- .

At page 11, line 4, please delete the underlining beneath the heading "Composition 1" so that it reads -- Composition 1 -- .

At page 11, line 27, please delete the underlining beneath the heading "Composition 2 to 5" so that it reads -- Composition 2 to 5 --.

At page 12, line 4, please delete the underlining beneath the heading "Composition 8 to 16" so that it reads -- Composition 8 to 16 -- .

At page 13, line 2, please delete the underlining beneath the heading "Compositions 17 to 24"so that it reads -- Compositions 17 to 24 -- .

At page 13, line 11, please delete the underlining beneath the heading "Compositions 25 to 33" so that it reads -- Compositions 25 to 33 -- .

At page 14, line 3, please delete the underlining beneath the heading "Compositions 34 to 42" so that it reads -- Compositions 34 to 42 -- .

At page 15, line 4, please delete the underlining beneath the heading "Compositions 43 to 58" so that it reads -- Compositions 43 to 58 -- .

At page 15, line 12, please delete the underlining beneath the heading "Examples of embodiments" so that it reads -- Examples of embodiments --.

At page 15, line 14, please delete the underlining beneath the heading "Example of stoppers" so that it reads -- Example of stoppers -- .

At page 15, line 16, please delete the underlining beneath the heading "Stopper n° 1" so that it reads -- Stopper n° 1 -- .

At page 17, line 2, please delete the underlining beneath the heading "Stopper n° 2" so that it reads -- Stopper n° 2 -- .

At page 17, line 11, please delete the underlining beneath the heading "Stopper n° 3" so that it reads -- Stopper n° 3 -- .

At page 17, line 23, please delete the underlining beneath the heading "Example of film" so that it reads -- Example of film -- .

At page 18, line 11, please delete the underlining beneath the heading "Example of tube" so that it reads -- Example of tube -- .

At page 19, line 3, please delete the underlining beneath the heading "CLAIMS" so that it reads -- CLAIMS --.

CLAIMS

Please cancel claims 1 - 29 as presented in the Annexes to the International Preliminary Examination Report.

Please add the following new claims:

30. Thermoplastic composition comprising:
a thermoplastic elastomer mixture containing at least a styrenic elastomer and a polyolefin resin, in which the thermoplastic elastomer mixture further comprises:
-- a not cross-linked thermoplastic SIS elastomer containing less than 20% by weight bound styrene, and
-- a thermoplastic elastomer which is at least partially cross-linked, the weight ratio of the not cross-linked thermoplastic SIS elastomer / thermoplastic elastomer at least partially cross-linked being comprised between 1:10 and 5:1.

31. The composition of claim 30, in which the not cross-linked SIS elastomer has a molecular weight comprised between 150,000 and 275,000.

32. The composition of claim 30, in which the not cross-linked SIS elastomer has a molecular weight comprised between 200,000 and 240,000.

33. The composition of claim 30, in which the weight ratio of the not cross-linked thermoplastic SIS elastomer / thermoplastic elastomer at least partially not cross-linked and polyolefin resin is comprised between 1:5 and 1:1.

34. The composition of claim 30, in which the polyolefin resin is selected from the group consisting of polyethylene, polypropylene, and mixtures of polyethylene and polypropylene.

35. The composition of claim 30, in which the polyolefin resin and the at least partially cross-linked thermoplastic elastomer forms a premixture containing not cross-linked thermoplastic elastomer and partially cross-linked thermoplastic elastomer.

36. The composition of claim 30, in which the at least partially cross-linked thermoplastic elastomer has a cross-linking rate of more than 20%.

37. The composition of claim 30, in which the at least partially cross-linked thermoplastic elastomer has a cross-linking rate comprised between 25% and 75%.

38. The composition of claim 30, in which the composition comprises as the thermoplastic elastomer and polyolefin resin, a mixture of polyolefin resin and SIS elastomer, the said mixture containing at least 40% by weight SIS elastomer, whereby the said mixture contains at least 20% by weight at least partially cross-linked SIS elastomer.

39. The composition of claim 30, further comprising a not cross-linked thermoplastic SIS elastomer and a thermoplastic elastomer which has been partially cross-linked in the presence of polyolefin, the weight ratio of not cross-linked thermoplastic SIS elastomer / thermoplastic elastomer which has been partly cross-linked in the presence of a polyolefin being comprised between 1:6 and 1:1.

40. The composition of claim 30, further comprising a polyolefin resin, a partly cross-linked thermoplastic elastomer and a not cross-linked thermoplastic SIS elastomer, the weight content of partially cross-linked elastomer with respect to the weight of polyolefin resin, partially cross-linked thermoplastic elastomer and not cross-linked thermoplastic SIS elastomer being comprised between 20% and 40%, while the weight content of not cross-linked thermoplastic SIS elastomer with respect to the weight of polyolefin resin, partially cross-linked thermoplastic elastomer and not cross-linked thermoplastic SIS elastomer being comprised between 15% and 50%.

41. The composition of claim 30, further comprising at least 20% by weight of a not cross-linked thermoplastic elastomer different from the not cross-linked thermoplastic SIS elastomer.

42. The composition of claim 41, in which the weight ratio of the not cross-linked thermoplastic elastomer different from the thermoplastic SIS elastomer / not cross-linked SIS thermoplastic elastomer is lower than 1:2.

43. The composition of claim 30, further comprising at least 20% by weight of a not cross-linked thermoplastic elastomer different from the not cross-linked thermoplastic elastomer, the weight ratio of the not cross-linked thermoplastic elastomer different from the thermoplastic SIS elastomer / not cross-linked SIS thermoplastic elastomer being lower than 1:10.

44. The composition of claim 30 in which the polyolefin resin and the thermoplastic elastomer(s) is a substantially homogeneous mixture of a substantially homogeneous premixture of a polyolefin and a partly cross-linked thermoplastic elastomer, with a not cross-linked thermoplastic SIS elastomer.

45. The composition of claim 30, in which a silane is used for the partial cross-linking of the thermoplastic elastomer.

46. The composition of claim 30, further comprising an amount of not cross-linked elastomer sufficient for ensuring a stability to a treatment selected from the group consisting of heat treatment at a temperature of at least 121°C of at least 100 minutes, γ irradiation of at least 20 KGray, and combinations thereof.

47. The composition of claim 30, further comprising at least an additive selected from the group consisting of dyes, pigments and mixtures thereof.

48. The composition of claim 30, which comprises less than 0.5% by weight halide salt.

49. The composition of claim 48, which comprises less than 0.2% by weight halide salt.

50. Sealing means for a container or vial, at least a part of the said sealing means being made of a composition comprising a thermoplastic elastomer mixture containing at least a styrenic elastomer and a polyolefin resin, in which the thermoplastic elastomer mixture comprises:

-- a not cross-linked thermoplastic SIS elastomer containing less than 20% by weight bound styrene, and
-- a thermoplastic elastomer which is at least partially cross-linked, the weight ratio of the not cross-linked thermoplstic SIS elastomer / thermoplastic elastomer at least partially cross-linked being comprised between 1:10 and 5:1.

51. The sealing means of claim 50, in which the not cross-linked SIS elastomer has a molecular weight comprised between 150,000 and 275,000.

52. The sealing means of claim 50, in which the not cross-linked SIS elastomer has a molecular weight comprised between 200,000 and 240,000.

53. The sealing means of claim 50, in which the polyolefin resin is selected from the group consisting of polyethylene, polypropylene, and mixtures of polyethylene and polypropylene.

54. The sealing means of claim 50, in which the polyolefin resin and the at least partially cross-linked thermoplastic elastomer forms a premixture containing not cross-linked thermoplastic elastomer and partially cross-linked thermoplastic elastomer.

55. The sealing means of claim 50, in which the composition further comprises as thermoplastic elastomer and polyolefin resin, a mixture of polyolefin resin and SIS elastomer, the said mixture containing at least 40% by weight SIS elastomer, whereby the said mixture contains at least 20% by weight at least partially cross-linked SIS elastomer.

56. The sealing means of claim 50, in which the composition further comprises a not cross-linked thermoplastic SIS elastomer and a thermoplastic elastomer which has been partially cross-linked in the presence of polyolefin, the weight ratio of not cross-linked thermoplastic SIS elastomer / thermoplastic elastomer which has been partly cross-linked in the presence of a polyolefin being comprised between 1:6 and 1:1.

57. The sealing means of claim 50, in which the composition further comprises a polyolefin resin, a partly cross-linked thermoplastic elastomer and a not cross-linked thermoplastic SIS elastomer, the weight content of partially cross-linked elastomer with respect to the weight of polyolefin resin, partially cross-linked thermoplastic elastomer and not cross-linked thermoplastic SIS elastomer being comprised between 20% and 40%, while the weight content of not cross-linked thermoplastic SIS elastomer with respect to the weight of polyolefin resin, partially cross-linked thermoplastic elastomer and not cross-linked thermoplastic SIS elastomer being comprised between 15% and 50%.

58. The sealing means of claim 50, in which the composition further comprises at least 20% by weight of a not cross-linked thermoplastic elastomer different from the not cross-linked thermoplastic SIS elastomer.

59. The sealing means of claim 58, in which the weight ratio of the not cross-linked thermoplastic elastomer different from the thermoplastic SIS elastomer / not cross-linked SIS thermoplastic elastomer is lower than 1:2.

60. The sealing means of claim 50, in which the polyolefin resin and the thermoplastic elastomer(s) is a substantially homogeneous mixture of a substantially homogeneous premixture of a polyolefin and a partly cross-linked thermoplastic elastomer, with a not cross-linked thermoplastic SIS elastomer.

61. The sealing means of claim 50, in which a silane is used for the partial cross-linking of the thermoplastic elastomer.

62. The sealing means of claim 50, in which the composition comprises an amount of not cross-linked elastomer sufficient for ensuring a stability to a treatment selected from the group consisting of heat treatment at a temperature of at least 121 °C during at least 100 minutes, γ irradiation of at least 20 KGray, and combinations thereof.

63. The sealing means of claim 50, in which the composition further comprises at least an additive selected from the group consisting of dyes, pigments and mixtures thereof.

64. The sealing means of claim 50, in which the composition comprises less than 0.5% by weight halide salt.

65. The sealing means of claim 64, in which the composition comprises less than 0.2% by weight halide salt.

66. In combination:

a pharmaceutical container or vial defining an inner volume and a surface;

sealing means for sealing said pharmaceutical container or vial, the said sealing means comprising a body, at least a part of the body being made of a composition comprising a thermoplastic elastomer mixture containing at least a styrenic elastomer and a polyolefin resin, in which the thermoplastic elastomer mixture comprises :

-- a not cross-linked thermoplastic SIS elastomer containing less than 20% by weight bound styrene, and

-- a thermoplastic elastomer which is at least partially cross-linked, the weight ratio of the not cross-linked thermoplastic SIS elastomer / thermoplastic elastomer at least partially cross-linked being comprised between 1:10 and 5:1,

the said body being associated to a layer contacting the surface of the vial or container when the sealing means closes the said container or vial.

67. The combination of claim 66, in which the polyolefin resin of the composition is selected from the group consisting of polyethylene, polypropylene, copolymer of ethylene-polypropylene and mixtures thereof, while the said layer is at least partly made of a polyolefin resin selected from the group consisting of polyethylene, polypropylene, copolymer of ethylene-polypropylene and mixtures thereof.

68. An element selected from the group consisting of film, bag, cloth, protecting cloth, tube, cap, and cap for protecting a needle of a syringe, said element comprising at least a layer made of a composition comprising a thermoplastic elastomer mixture containing at least a styrenic elastomer and a polyolefin resin, in which the thermoplastic elastomer mixture comprises:

-- a not cross-linked thermoplastic SIS elastomer containing less than 20% by weight bound styrene, and

-- a thermoplastic elastomer which is at least partially cross-linked,

the weight ratio of the not cross-linked thermoplastic SIS elastomer / thermoplastic elastomer at least partially cross-linked being comprised between 1:10 and 5:1.

69. The element of claim 68, in which the polyolefin resin of the composition is selected from the group consisting of polyethylene, polypropylene, copolymer of ethylene-polypropylene and mixtures thereof, while the element further comprises at least one layer consisting essentially of a polyolefin resin selected from the group consisting of polyethylene, polypropylene, copolymer of ethylene-propylene and mixtures thereof.

70. The element of claim 68, which further comprises a second layer made of said composition.

71. Process for the manufacture of an article from a composition comprising a thermoplastic elastomer mixture containing at least a styrenic elastomer and a polyolefin resin in which the thermoplastic elastomer mixture comprises:

-- a not cross-linked thermoplastic SIS elastomer containing less than 20% by weight bound styrene, and

-- a thermoplastic elastomer which is at least partially cross-linked,

the weight ratio of the not cross-linked thermoplastic SIS elastomer / thermoplastic elastomer at least partially cross-linked being comprised between 1:10 and 5:1, in which the said composition is mixed at a temperature sufficient for the at least partial melting of the not cross-linked SIS elastomer, and in which the said composition is thereafter formed into the said articles.

72. The process of claim 71, in which the said composition contains at least one additive selected from the group consisting of dyes, pigments and mixtures thereof and having a melting point corresponding substantially to the melting point of the not cross-linked SIS elastomer, in which a control of the additive distribution in the formed articles is carried out, and in which the mixing step is controlled so as to reach a substantially homogeneous distribution of said additive in a part of the composition just before its formation into the said article.

73. The process of claim 71, in which the said article is sterilized by a treatment selected from the group consisting of heating at a temperature of at least 121 °C during at least 100 minutes, irradiation with a γ-irradiation of at least 20 KGray, and combinations thereof.